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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,187	03/03/2004	Valery A. Petrenko	035721/274140	4902

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EXAMINER

YU, MELANIE J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/792,187

Applicant(s)

PETRENKO ET AL.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 28 September 2005 has been entered. Claims 1 and 2 have been withdrawn. Claims 4-20 have been canceled. Claims 1-3 are currently pending in this application.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is vague and indefinite because it is a product that is made by a specific process. It is unclear what product limitations result from the process. The only product limitation required for the current product is a monolayer because no other specific product limitations have been recited as essential to the product. For instance, it is unclear what product limitations result from delivering a composition at a specific rate. Furthermore, it is unclear what composition results from a stripped phage. It is unclear if the monolayer must comprise a stripped phage, and what other product requirements are encompassed by the monolayer recited in claim 3.

Claim Rejections - 35 USC § 102

3. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Hengerer et al. (Quartz crystal microbalance as a device for the screening of phage libraries, 1999, Biosensors & Bioelectronics, Vol. 14, pgs. 139-144).

Hengerer et al. teach a monolayer (pg. 140, section 2.2).

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4. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Benjamin et al. (US 2001/0006778).

Benjamin et al. teach a cell monolayer (par. 0058).

5. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Uttenthaler et al. (Quartz crystal biosensor for detection of the African Swine Fever disease, 1998, *Analytica Chimica Acta*, Vol. 362, pages 91-100).

Uttenthaler et al. teach a layer of VP73 receptors (Fig. 1; pg. 95, section 3.1, first paragraph), which encompasses a monolayer.

Although Hengerer et al., Benjamin et al. and Uttenthaler et al. do not specifically teach the method of forming recited in withdrawn claim 1, both teach a monolayer as disclosed above. It is unclear what further product limitations would be provided by the recited method and therefore, Hengerer et al., Benjamin et al. and Uttenthaler et al. teach the product recited in claim 3.

Double Patenting

6. Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of copending Application No. 09/452,968. Although the conflicting claims are not identical, they are not patentably distinct from each other because the monolayer of claim 18 is encompassed by any monolayer as recited in claim 3 of the instant application.

7. Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 20 of copending Application No. 10/068,570. Although the conflicting claims are not identical, they are not patentably distinct

from each other because a layer comprising a peptide is encompassed by a monolayer as recited in claim 3 of the instant application.

8. Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of copending Application No. 10/289,725. Although the conflicting claims are not identical, they are not patentably distinct from each other because a layer of biotinylated lipid is encompassed by a monolayer as recited by instant claim 3.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 28 September 2005 have been fully considered but they are not persuasive. Applicant argues that Hengerer et al. fail to teach monolayers comprising stripped phage that are created using a particular purification process. Applicant argues that Benjamin et al. fail to teach a monolayer of a stripped phage prepared by a specific purification process. Uttenthaler et al. fail to teach a monolayer comprising a stripped phage prepared by a specific purification process. Applicant also argues that the obviousness-type double patenting rejections do not comprise a stripped phage and the references recited unrelated monolayers. Applicant argues that the claimed product can only be adequately defined by the process steps by which the product is made and cites MPEP §2113: The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart

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distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979).

In response to applicant's arguments, it should be noted that according to MPEP §2113: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Applicant argues that the product is defined by manufacturing process steps that would be expected to impart distinctive structural characteristics to the final product. However, the manufacturing steps recited in claim 3 form a monolayer as recited, which do not impart distinctive structural characteristics to the final product because the prior art structurally teaches a monolayer which would be the same product that is produced by the method recited in claim 3. Even though applicant has claimed the process by which the product is formed, the determination of patentability is based on the product itself, and the product does not depend on its method of production. The product produced by the method recited in claim 3 is a monolayer. Therefore, even though the products of Benjamin et al., Uttenthaler et al. and Hengerer et al. are made by different processes, a monolayer product is taught, which is the same product produced by the method of claim 3. Any further product limitations, such as if the monolayer comprises a stripped phage, must be claimed as part of the monolayer product and not recited as part of a process of forming a monolayer.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melanie Yu
Patent Examiner
Art Unit 1641



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12/20/05